



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	09/924,319
Filing Date	8/8/01
First Named Inventor	Gerard P. McNally
Group Art Unit	1616
Examiner Name	Choi
Attorney Docket Number	MCP-0289

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Code <sup>2</sup> Number known)	Kind (if			
JL		4,195,084		Ong, J.	3/25/80	RECEIVED JAN 09 2002 TECH CENTER 1600/2900
		5,120,533		Schmidt et al.	6/9/92	
		5,277,902		Schmidt et al.	1/11/94	
		5,393,745		Schmidt et al.	2/28/95	
		5,418,220		Schmidt et al.	5/23/95	
		5,424,064		Schmidt et al.	6/13/95	
		5,525,605		Omura, S.	6/11/96	
		5,599,577		Stevens et al.	2/4/97	
		5,679,376		Stevens et al.	10/21/97	
		5,716,641		Stevens et al.	2/10/98	
		5,834,004		Upmeyer et al.	11/10/98	
		5,843,479		Kelm et al.	12/1/98	
		5,848,403		Borody et al.	Jan. 1999	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
JL		WO	95/25545		PCT	9/28/95		
JL		FR	57,566		France	11/20/67		

Examiner  
Signature*Jim Ebb*Date  
Considered*9/5/02*

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



PTO/SB/08A (08-00)  
Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	09/924,319
Filing Date	8/8/01
First Named Inventor	Gerard P. McNally
Group Art Unit	1616
Examiner Name	Chen
Attorney Docket Number	MCP-0289

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
A		Brouwers et al.; A Controlled Trial of Senna Preparations and Other Laxatives Used for Bowel Cleaning Prior to Radiological Examination; Pharmacology 20, Suppl. 1, 1980, pp.58-64.
		McNally et al.; The Effect of Simethicone on Colonic Visibility after Night-Prior Colonic Lavage, A Double-Blind Randomized Study; J. Clin. Gastro, 1989;11(6) pp. 650-652
		Kark et al.; Improvement of Orthograde Golytely Colon Lavage by Additional Application of Simethicone; Gastroenterol 1995; 33: pp. 20-23
		Lazzaroni et al.; Efficacy and Tolerability of Polyethylene Glycol-Electrolyte Lavage Solution With and Without Simethicone in the Preparation of Patients with Inflammatory Bowel Disease for Colonoscopy; Aliment Pharmacol Ther. 1993; 3: pp. 655-659
		Shaver et al.; Improvement of Oral Colonic Lavage with Supplemental Simethicone; Digestive Diseases and Sciences, Vol. 33, No. 2, Feb '88, pp. 185-188
		Campieri et al.; Better Quality of Therapy with 5-ASA Colonic Foam in Active Ulcerative Colitis; A Multicenter Comparative Trial with 5-ASA; Inst. Of Clin.ed & Gastro., Univ. of Bologna, Italy; Dig-Dis-Sci., Oct. 1993, 38(10); pp. 1843-50 (abstract)
		Information Leaflet (3/1/95) for PURGO-PIL 10 mg
		McNally et al., The Effectiveness of Simethicone in Improving Visibility During Colonoscopy; A Double-Blind Randomized Study; Gastro. Endo., Vol. 34, No. 3, 1988, pp. 255-258
		Sudduth et al.; The Effectiveness of Simethicone in Improving Visibility During Colonoscopy When Given with a Sodium Phosphate Solution; a Double-Blind Randomized Study; Gastro. End Vpol. 52, No. 5, 1995, pp. 513-415
		Pankh & Khanduja; Use of Simethicone During Colonoscopy; Dis Colon Rectum, Sept. 1995, Letters to the Editor, pp. 100-1008
		Igor Laufer, "A Simple Method for Routine Double-Contrast Study of the Upper Gastrointestinal Tract" (Radiology, Vol. 117, No. 3, 1975) pp.513-518
		Kuzo K. Kimura, Joseph R. Treon, Frederick R. Benson "Therapeutic Use of Methylopolysiloxane" (Current Therapeutic Research, Vol. 5, No. 3 (1964) pp. 202-215
		D.M. Presont, J.E. Lennard-Jones "Pelvic Motility and Response to Intraluminal Bisacodyl in Slow-Transit Constipation" (Digestive Diseases and Sciences, Vol. 30, No. 4, (1985) pp. 289-294
		Von w. Roth, Unter Mitabeit von K. Beschke "Pharmakokinetik und Laxierende Wirkung von Bisacodyl nach Gabe verschiedener Zuberreitungsformen (Araneim-Forsch/Drug Res. 38(I), Nr. 4 1998) pp. 470-574
		Stephan R. Targan "The Search for Pathogenic Antigens in Ulcerative Colitis" (Gastroenterology, Vol. 114, No. 5, 1998) pp.1099-1100
		STN/CAS online, file DRUGLAUNCH, Acc. No. 94:53778, Doc. No. 0107008 (Drug Launches 1993)
		STN/CAS online, file EMBASE, Acc. No. 91205342, Doc. No. 1991205342 (Widgrube et al., Bildgebung (1991) 58/2 (63-66) Abstract

Examiner Signature	<i>John Chen</i>	Date Considered	9/5/02
--------------------	------------------	-----------------	--------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.